Express Mail Label: EL752686671US Date of Deposit: March 22, 2002

Attorney Docket No. 22493-501 (Symb

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Kurtis et al.

SERIAL NUMBER:

10/008,340

EXAMINER:

Not Yet Assigned

FILING DATE:

November 13, 2001

ART UNIT:

1619

For:

SUSTAINED BIOACTIVE AGENT DELIVERY DEVICE AND

METHODS OF MAKING AND USING THE SAME

#### **Box IDS**

**Assistant Commissioner for Patents** Washington, D.C. 20231

#### TRANSMITTAL LETTER

Transmitted herewith for filing in the above-referenced patent application are the following documents:

- 1. Information Disclosure Statement (4 pages);
- 2. Modified Form 1449/PTO (2 pages), in duplicate;
- 3. Copies of cited references A1, C1-C22; and
- 4. Return postcard.

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at 617-542-6000, Boston, Massachusetts.

The Commissioner is authorized to charge any additional fees that may be due, or to credit any overpayment, to the undersigned's account, Deposit Account No. 50-0311 Ref. No. 22493-501 (SymbionT-1). A duplicate copy of this transmittal letter is enclosed herewith.

Respectfully submitted,

Attorney for Applicant

Ivor R. Elrifi, Reg. No. 39,529

c/o

MINTZ, LEVIN, COHN, FERRIS GLOVSKY AND POPEO, P.C.

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Date: March 22, 2002



PATENT TRADEMARK OFFICE

TRA 1610045v1

Express Mail Label No.: EL752686671US

Date of Deposit: March 22, 2002

Attorney Docket No. 2249

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

LICANT: Kurtis et al.

EXAMINER: Not Yet Assigned

Assignee:

SymbionT

**ART UNIT: 1619** 

SERIAL NUMBER: 10/008,340

FILING DATE: November 13, 2001

FOR: SUSTAINED BIOACTIVE AGENT DELIVERY DEVICE AND

METHODS OF MAKING AND USING THE SAME

**Assistant Commissioner for Patents** 

Washington, D.C. 20231

## INFORMATION DISCLOSURE STATEMENT

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97, and 1.98, Applicant hereby makes of record the attached documents listed below and on the attached modified Form PTO-1449 (submitted in duplicate) in the above-identified application. The order of presentation of the references should not be construed as an indication of the importance of the references. Reference C9 is in French, therefore, only the English summary is provided.

## **U.S. Patent Documents**

6,020,144

## Non Patent Literature Documents:

Fire, A. and Waterston, R.H. (1989) Proper expression of myosin genes in transgenic nematodes [published erratum appears in EMBO J 1989 Dec;8(13):4359]. EMBO J. 8, 3419-3428.

Robbins, P.D. et al. (1998) Viral vectors for gene therapy. Trends In Biotechnology 16, 35-40.

Pieroni, L. et al. (1998) Targeted integration of adeno-associated virus-derived plasmids in transfected human cells. Virology 249, 249-259.

Basch, P.F. and Rhine, W.D. (1983) Schistosoma mansoni: reproductive potential of male and female worms cultured in vitro. J. Parasitol. 69, 567-569.

Newport, G.R. and Weller, T.H. (1982) Miracidia infective for snails derived from eggs laid

by adult Schistosoma mansoni in vitro. Parasitology 84, 481-490.

- Kawanaka, M. et al. (1985) In vitro transformation of Schistosoma japonicum miracidia to young sporocysts in a culture system for egg maturation. J. Parasitol. 71, 368-370.
- Yoshino, T.P. and Laursen, J.R. (1995) Production of Schistosoma mansoni daughter sporocysts from mother sporocysts maintained in synxenic culture with Biomphalaria glabrata embryonic (Bge) cells. *J. Parasitol.* 81, 714-722.
- DiConza, J.J. and Hansen, E.L. (1972) Multiplication of transplanted Schistosoma mansoni daughter sporocysts. *J. Parasitol.* 58, 181-182.
- Jourdane, J. (1984) Maintenance of a male and a female clone of Schistosoma mansoni by microsurgical transplantation of sporocysts. Reliability of the method. [French].

  Annales de Parasitologie Humaine et Comparee 59, 361-367.
- Cohen, L.M. and Eveland, L.K. (1984) Schistosoma mansoni: long-term maintenance of clones by microsurgical transplantation of sporocysts. *Exp. Parasitol.* 57, 15-19.
- Cohen, L.M. and Eveland, L.K. (1988) Schistosoma mansoni: characterization of clones maintained by the microsurgical transplantation of sporocysts. *J. Parasitol.* 74, 963-969.
- Purnell, R.E. (1966) Host-parasite relationships in schistosomiasis. II. The effects of age and sex on the infection of mice and hamsters with cercariae of Schistosoma mansoni and of hamsters with cercariae of Schistosoma haematobium. *Annals of Tropical Medicine & Parasitology* 60, 94-99.
- Davis, R.E. et al. (1999) Transient expression of DNA and RNA in parasitic helminths by using particle bombardment. *Proc. Natl. Acad. Sci. USA* 96, 8687-8692.
- Transfection of *Brugia Malayi*. Unnasch TR, Higazi TB, Merriweather A, and Davis, RE. Division of Geographic Medicine, University of Alabama at Birmingham, AL; and Biological Sciences, Fordham University. Abstract #203. American Society of Tropical Medicine and Hygiene, 49<sup>th</sup> Annual Meeting, Houston, TX.
- Abdeen, H.H. et al. (1999) Molecular cloning and characterization of the polypeptide backbone of Schistosoma mansoni circulating cathodic antigen. Mol. Biochem. Parasitol. 101, 149-159.
- Brady, C.P. et al. (1999) Recombinant expression and localization of Schistosoma mansoni cathepsin L1 support its role in the degradation of host hemoglobin. *Infect. Immun.* 67, 368-374.

APPLICANTS: U.S.S.N.:

Kurtis et al. 10/008,340

Dalton, J.P. et al. (1996) Characterization of the cathepsin-like cysteine proteinases of Schistosoma mansoni. *Infect. Immun.* 64, 1328-1334.

Khalife, J. et al. (1995) Transcriptional regulation of Schistosoma mansoni calreticulun: possible role of AP-1. Parasitology 111, 469-475.

Skelly, P.J. and Shoemaker, C.B. (1996) Rapid appearance and asymmetric distribution of glucose transporter SGTP4 at the apical surface of intramammalian-stage *Schistosoma* mansoni. Proc. Natl. Acad. Sci. USA 93, 3642-3646.

Grevelding, C.G. et al. (1997) Female-specific gene expression in Schistosoma mansoni is regulated by pairing. Parasitology 115, 635-640.

Giannini, A.L.M. et al. (1995) F-10 nuclear binding proteins of Schistosoma mansoni: structural and functional features. Parasitology 110, 155-161.

Rumjanek, F.D. (1989) Regulation of gene expression in the *Schistoma mansoni* female. Mem. Inst. Oswaldo Cruz 84, 197-198.

This Information Disclosure Statement is being been filed more than three months after the filing date of this application but before the mailing date of either an office action under 37 C.F.R. §1.113 or a Notice of Allowance under 37 C.F.R. §1.311. Accordingly, no fee is required as set forth in 37 C.F.R. §1.97.

It is respectfully requested that the Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims, and signs the enclosed form PTO-1449 to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that: (1) a search has been performed, of the extent of any search performed, or that more relevant information does not exist; (2) the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b); and (3) the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

**APPLICANTS:** 

Kurtis et al. 10/008,340

U.S.S.N.:

Notwithstanding any statements by the Applicants, the Examiner is urged to form his/her own conclusion regarding the relevance of the cited information. An early and favorable action is hereby requested. Please charge any additional fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311 (Reference No. 22493-501).

Respectfully submitted,

Ivor R. Elrifi, Reg. No. 39,529

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TRA 1632161v1

Date: March 22, 2002

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Page 1 of

10/008,340 **Application Number** Modified Form 1449/PTO 11/13/01 Filing Date Kurtis **First Named Inventor** INFORMATION DISCLOSURE STATEMENT BY APPLICANT 1619 Group Art Unit **Examiner Name** (use as many sheets as necessary) Attorney Docket Number 22493-501

U.S. PATENT DOCUMENTS							
Exam Initials	Cite No.	U.S. Patent Document No.	Issue Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date If Appropriate
	A1	6,020,144		Symbiontics, Inc.			

FOREIGN PATENT DOCUMENTS						
Exam Initials	Cite No.	Foreign Patent Document Office Number	Name of Patentee(s) or Applicant(s)	Date of Publication	Translation Yes No	
	B1					

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS				
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.		
	C1	Fire, A. and Waterston, R.H. (1989) Proper expression of myosin genes in transgenic nematodes [published erratum appears in EMBO J 1989 Dec;8(13):4359]. <i>EMBO J</i> 8, 3419-3428.		
	C2	Robbins, P.D. et al. (1998) Viral vectors for gene therapy. Trends In Biotechnology 16, 35-40.		
	СЗ	Pieroni, L. et al. (1998) Targeted integration of adeno-associated virus-derived plasmids in transfected human cells. Virology 249, 249-259.		
,	C4	Basch, P.F. and Rhine, W.D. (1983) Schistosoma mansoni: reproductive potential of male and female worms cultured in vitro. <i>J. Parasitol.</i> 69, 567-569.		
	C5	Newport, G.R. and Weller, T.H. (1982) Miracidia infective for snails derived from eggs laid by adult Schistosoma mansoni in vitro. <i>Parasitology</i> 84, 481-490.		
-	C6	Kawanaka, M. et al. (1985) In vitro transformation of Schistosoma japonicum miracidia to young sporocysts in a culture system for egg maturation. J. Parasitol. 71, 368-370.		
_	C7	Yoshino, T.P. and Laursen, J.R. (1995) Production of Schistosoma mansoni daughter sporocysts from mother sporocysts maintained in synxenic culture with Biomphalaria glabrata embryonic (Bge) cells. <i>J. Parasitol.</i> 81, 714-722.		
_	C8	DiConza, J.J. and Hansen, E.L. (1972) Multiplication of transplanted Schistosoma mansoni daughter sporocysts. <i>J. Parasitol.</i> 58, 181-182.		
dr	C9	Jourdane, J. (1984) Maintenance of a male and a female clone of Schistosoma mansoni by microsurgical transplantation of sporocysts. Reliability of the method. [French]. <i>Annales de Parasitologie Humaine et Comparee</i> 59, 361-367.		
_	C10	Cohen, L.M. and Eveland, L.K. (1984) Schistosoma mansoni: long-term maintenance of clones by microsurgical transplantation of sporocysts. <i>Exp. Parasitol.</i> 57, 15-19.		
•	C11	Cohen, L.M. and Eveland, L.K. (1988) Schistosoma mansoni: characterization of clones maintained by the microsurgical transplantation of sporocysts. <i>J. Parasitol.</i> 74, 963-969.		
	C12	Purnell, R.E. (1966) Host-parasite relationships in schistosomiasis. II. The effects of age and sex on the infection of mice and hamsters with cercariae of Schistosoma mansoni and of hamsters with		

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		OTHER PRIOR ART - NON PAGE LITERATURE DOCUMENTS TECH CENTER 16				
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.				
		cercariae of Schistosoma haematobium. Annals of Tropical Medicine & Parasitology 60, 94-99.				
	C13	Davis, R.E. et al. (1999) Transient expression of DNA and RNA in parasitic helminths by using particle bombardment. <i>Proc. Natl. Acad. Sci., U S A</i> 96, 8687-8692.				
-	C14	Transfection of <i>Brugia Malayi</i> . Unnasch TR, Higazi TB, Merriweather A, and Davis, RE. Division of Geographic Medicine, University of Alabama at Birmingham, AL; and Biological Sciences, Fordham University. Abstract #203. American Society of Tropical Medicine and Hygiene, 49 <sup>th</sup> Annual Meeting, Houston, TX.				
	C15	Abdeen, H.H. et al. (1999) Molecular cloning and characterization of the polypeptide backbone of Schistosoma mansoni circulating cathodic antigen. Mol. Biochem. Parasitol. 101, 149-159.				
	C16	Brady, C.P. et al. (1999) Recombinant expression and localization of Schistosoma mansoni cathepsin L1 support its role in the degradation of host hemoglobin. <i>Infect. Immun.</i> 67, 368-374.				
-	C17	Dalton, J.P. et al. (1996) Characterization of the cathepsin-like cysteine proteinases of Schistosoma mansoni. <i>Infect. Immun.</i> 64, 1328-1334.				
7	C18	Khalife, J. et al. (1995) Transcriptional regulation of Schistosoma mansoni calreticulun: possible role of AP-1. Parasitology 111, 469-475.				
	C19	Skelly, P.J. and Shoemaker, C.B. (1996) Rapid appearance and asymmetric distribution of glucose transporter SGTP4 at the apical surface of intramammalian-stage <i>Schistosoma mansoni</i> . <i>Proc. Natl. Acad. Sci. USA</i> 93, 3642-3646.				
	C20	Grevelding, C.G. et al. (1997) Female-specific gene expression in <i>Schistosoma mansoni</i> is regulated by pairing. <i>Parasitology</i> 115, 635-640.				
	C21	Giannini, A.L.M. et al. (1995) F-10 nuclear binding proteins of Schistosoma mansoni: structural and functional features. Parasitology 110, 155-161.				
	C22	Rumjanek, F.D. (1989) Regulation of gene expression in the <i>Shistosoma mansoni</i> female. Mem. Inst. Oswaldo Cruz 84, 197-198.				

35 U.S.C. §120 (continuation, continuation-in-part, and divisional applications). Date Examiner Considered Signature

\_\_, and relied upon for an earlier filing date under

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered.

Include copy of this form with next communication to applicant.

, filed